

Urgent Safety Information*Recall*

concerning

VenoTrain clinic medical compression stockings
as a result of incorrect packaging labels

September 7, 2021

Sender:

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Recipient:

Medical retailers and pharmacies that have ordered the “VenoTrain clinic” medical compression stockings from Bauerfeind AG during the specified period.

Identification of affected medical products:

“VenoTrain clinic” medical compression stockings: batches that were packaged and shipped between July 22 and August 31, 2021. A list with the numbers of the affected batches is enclosed.

Description of the issue including the reason:

Issue: the date specification, i.e. the expiration date, behind the “Use by” symbol (hour glass) is missing on the packaging labels of “VenoTrain clinic” medical compression stockings from the batches that were packaged and shipped between July 22 and August 31, 2021.

Medical compression stockings are medical products with a limited shelf life. If the date specification is missing, medical retailers and pharmacists cannot tell up to which date the products can be given to patients without posing a risk. That is why the products without date specification have to be recalled.

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Correct label:



Faulty label:



Reason: as a result of an operating error, an incorrect label type was selected for the affected batches. The error was immediately corrected after its detection, and labeling strictly checked using additional measures.

Risks for patients: the product itself is not faulty; it is safe.

Patients who have received products from the affected batches are not at risk because they have been given products that were manufactured in July or August 2021. The expiration date for these medical compression stockings is January or February 2025, respectively. Medical compression stockings are intended for immediate use after they have been issued. The average wearing duration is six to twelve months. Medical retailers regularly (once or twice a year) check the measurements of patients in Germany and subsequently issue new medical compression stockings.

What action does the recipient need to take?

All affected medical retailers and pharmacies will receive "Urgent Safety Information" from Bauerfeind AG and are asked to return the affected products. At the same time, the relevant sales staff will get in touch with the customers in question. Returns are handled in accordance with Bauerfeind AG's Returns Policy which allows a credit note or replacement. Additionally, medical retailers can order new goods straight away.

Schedule:

- from September 8 to 17, 2021, all affected medical retailers and pharmacies will be notified: in writing via "Urgent Safety Information" as well as by the relevant sales staff.
- All products should be returned by October 31, 2021.
- On November 15, 2021, the BfArM (Federal Institute for Drugs and Medical Devices) will receive the closing report.

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